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## Description

This invention relates to a guiding catheter and particularly to a guiding catheter for aid in insertion of a pacing catheter.

A pacing catheter and a pulse generator are used to electrically stimulate or pace the heart. To accomplish this, the catheter is inserted through a vein into the heart. Typically, the catheter is inserted into the right ventricle.

One way to insert a cardiac pacing catheter or other inner catheter is to advance it through the lumen of a pulmonary artery guiding catheter. To accomplish this, the guiding catheter must first be inserted through a vein and the right heart to the pulmonary artery, and this requires that the guiding catheter be formed in a curve in the right ventricle. The guiding catheter has a port within or adjacent the curve through which the pacing catheter can extend. One problem with this composite guiding catheter-pacing catheter system is that the guiding catheter tends to form a sharp reverse bend or kink immediately distally of the port, and this is undesirable in that the kink can close off the lumens in the guiding catheter.

The guiding catheter is of necessity flexible, long and of very small diameter. It is inherently difficult to control the orientation of the port in a device of this type because the port tends to rotate about the long axis of the catheter. Proper control of the angular orientation of the port is important because port orientation materially influences the location of the pacing catheter in the heart.

EP-A-0109178 discloses a guiding catheter capable of being passed through the right side of the heart into the pulmonary artery, said guiding catheter comprising:

an elongated catheter body having proximal and distal ends, at least one lumen extending longitudinally in the body and a port extending from a lumen to the exterior of the catheter body, said port being positioned in relation to the distal end of the catheter such that said port lies in the right ventricle when the catheter extends through the right ventricle into the pulmonary artery;

an elongated stiffening element permanently fixed within the catheter body, said stiffening element extending from a location on the proximal side of said port to a location on the distal side of said port, said stiffening element being flexible and sufficiently stiff to cause the catheter to form a gentle curve without forming a kink when the catheter extends through the right ventricle to the pulmonary artery; and

said lumen being such that an inner catheter can be passed through the lumen and the port into the right ventricle.

This invention provides a guiding catheter according to EP-A-0109178 but in which said stiffening element is curved in its unstressed condition so that said catheter body in the region of the port that extends from the lumen to the exterior of the catheter body is curved, said stiffener element is held against rotation in the catheter body and said stiffener element resists torsional displacement of the port.

The stiffening element, such as an elongated polymeric or metallic rod or wire, is permanently fixed, as by bonding, within the guiding catheter. The stiffening element begins proximal to the port and extends to a location distal to the port so that the region through the port and distally thereof is stiffened. Preferably, the stiffening element terminates no farther distally than the right ventricle and no farther proximally than the superior vena cava, when the catheter system is used for pacing the right ventricle, the stiffening element preferably terminates at its opposite ends in the right atrium and the right ventricle. In a preferred construction, the curve on the stiffening element is circular and extends for over 180°.

The stiffening element materially reduces the tendency of the guiding catheter to twist so as to harmfully disorient the port in a plane taken radially of the catheter. In addition, the stiffening element prevents the catheter port from rotating about the longitudinal axis of the catheter during sterilisation and packaging of the catheter. Accordingly, a pacing catheter can be directed to the desired location in the heart with much greater accuracy.

The orientation of the port in a radial plane is important in guiding the inner catheter to the desired location. For a pacing catheter, the center of the port should be generally on the outside of the curve, and preferably, the center of the port as viewed in a radial plane forms an angle of no more than about 30 degrees with a radial reference line which bisects the portion of the curve which faces outside.

To facilitate the passage of the inner catheter through the port into the right heart, the lumen containing the port is preferably at least partially closed. Such closing means preferably includes a sloping surface facing proximally in the lumen to guide the inner catheter out through the port. To permit the port to be accurately located when the catheter is within the body, the closing means can advantageously include a radiopaque plug.

The guiding catheter of this invention is particularly adapted for use with a pacing catheter, although it may be used with various inner catheters of different constructions. As used herein, the terms pacing catheter and inner catheter include both catheters and probes which may be passed through an outer or guiding catheter.

The invention, together with additional features and advantages thereof, may best be understood by reference to the following exemplary description taken in connection with the accompanying illustrative drawings, in which :

Fig. 1 is a sectional view through a human heart showing one way in which the catheter of this invention can be used.

Fig. 2 is an elevational view of a guiding catheter laid out flat and constructed in accordance with the teachings of this invention.

Fig. 3 is an enlarged, fragmentary elevational view of the proximal portion of the catheter which is designated by the bracket 7 of Fig. 2.

Fig. 4 is a fragmentary, sectional view of the catheter illustrating the thermistor and the adjacent region of the catheter.

Fig. 5 is an enlarged, section view taken generally along line 9-9 of Fig. 2.

Fig. 6 is an enlarged, fragmentary sectional view taken generally along line 10-10 of Fig. 2 with the portions shown in Fig. 6 being in the generally arcuate configuration which it assumes in packaging and when unstressed.

Fig. 7 is an elevational view of the construction shown in Fig. 6.

Fig. 8 is an enlarged, section view taken generally along line 12-12 of Fig. 6.

Fig. 9 is a plan view of one form of stiffening element.

Fig. 1 shows how the guiding catheter 63 of this invention can be used to guide and direct an inner catheter. The guiding catheter 63 is described generally with reference to Fig. 1 and, more specifically, with reference to Figs. 2 to 9. Considering first the general description of Fig. 1, the guiding catheter 63 has a catheter body 101 which may be inserted into the heart through a vein using conventional techniques. Following such insertion, a balloon 65 adjacent the distal end of the guiding catheter 63 is lodged in the pulmonary artery 67. As shown in Fig. 1 the guiding catheter 63 extends through the superior vena cava 66 and is formed into a curve 68 of about 180 degrees as it extends through the right atrium 69 and the right ventricle 71. The guiding catheter 63 has a port 72 leading from one of its lumens into the right ventricle 71.

In the embodiment illustrated, the stiffening element 64 is in the form of an elongated, flexible, resilient rod or wire of metal, elastomer or plastic bonded into the guiding catheter 63 outside of the lumen with which the port 72 communicates.

According to the invention the stiffening element 64 is curved in its unstressed condition and forms the catheter body 101 into a curve in the region of port 72. In the preferred construction illustrated, the stiffening element 64 extends from a

location in the right atrium 69 proximally of the port 72 continuously to a location in the right ventricle 71 located distally of the port 72. Thus, regions of the guiding catheter adjacent the port 72 on the opposite sides of the port 72 are stiffened, and such stiffening is controlled to cause the catheter 63 to form the relatively gentle curve 68 in the right heart without kinking as the catheter extends through the right heart to the pulmonary artery 67.

With the guiding catheter 63 positioned in the right heart as shown in Fig. 1 the catheter 11 can be inserted through a lumen of the guiding catheter 63 and out of the port 72. As the catheter 11 continues its advancing movement, electrode 62 of catheter 11 contacts the wall 73 of the right ventricle and bends over or deflects along the wall due to the resilience of the distal section 41 of catheter 11 all the way to the distal end 48. This causes the electrode 62 and the transition section 39 of catheter 11 to resiliently flex and causes the electrode to lie against the wall 73 without penetrating the wall. A circuit can then be completed from the electrode 62 through the heart wall 73 and body fluids in the heart to the electrode 35.

Figs. 2-9 show a preferred form of the guiding catheter 63 in greater detail. The catheter body 101 in the embodiment illustrated, has a through lumen 103 (Fig. 8), a stiffener lumen 105, a balloon inflation lumen 107 and a guiding lumen 109. The catheter body 101 terminates proximally in a hub 111, and each of the lumens 103, 105, 107 and 109 terminate proximally at the proximal end of the catheter body. Connector tubes 113, 115, 117 and 119 are mounted within the proximal ends of the lumens 103, 105, 107 and 109, respectively, in a conventional manner.

The through lumen 103 extends completely through the catheter body 101 to a distal end 121 (Fig. 5), and the balloon inflation lumen 107 extends to a location adjacent the distal end 121 where it communicates with the interior of the balloon 65 via a port 123. The balloon 65 is retained on the catheter body 101 in a conventional manner.

A thermistor 125 (Figs. 2 and 4) is suitably mounted in the stiffener lumen 105 as by potting 126 and is exposed by a port 127 in the stiffener lumen. Thermistor wires 129 extend proximally from the thermistor 125 through the stiffener lumen 105 to a location adjacent an injectate port 131 (Fig. 2) in the stiffener lumen, and at this location the thermistor wires 129 cross over into the balloon inflation lumen 107. The cross over of the thermistor wires 129 between lumens may be accomplished as shown in Lieber et al U.S. Patent No. 4,329,993. The thermistor wires 129 extend from the cross-over location to the connector tube 117 in the balloon inflation lumen 107.

The guiding lumen 109 extends to the port 72 (Fig. 6.), and the lumen is closed just distally of the port 72 by a plug 133 of suitable radiopaque material, such as a mixture of polyvinylchloride and tantalum. The plug 133 has a sloping surface 135 which is inclined distally as it extends outwardly toward the port 72 to facilitate the passage of the inner catheter 11 through the port 72 into the right heart. To further facilitate exit of the inner catheter 11, the port 72 is preferably elongated in a direction axially of the catheter body 101.

The stiffening element 64 may be of various different constructions, and in the embodiment illustrated in Fig. 9, it includes a nylon core or rod 137 encased within a tube or jacket 139 of a suitable plastic, such as PVC. The rod 137 is preformed into an arc and, preferably, is preformed into a circular arc. Although the extent of the circular arc can vary, preferably, it extends for over 180 degrees, and about 240 degrees is considered generally optimum. The preforming of the nylon rod 137 can be carried out at elevated temperatures. Thereafter, the tube 139 is shrunk over the rod. The rod 137 has opposite ends 141, and between such ends, the stiffening element 64 is of essentially constant cross section such that the stiffness of this relatively large central section is substantially constant. To provide the stiffening element with end portions of somewhat lesser stiffness than the central section, the tube 139 extends for a short distance beyond the ends 141. For example, in a case where the stiffening element 64 is about four inches in length the tube 139 may project about .1 to about .2 inch (2.5 to 5mm) beyond each of the ends 141.

The stiffening element 64 is inserted through the stiffener lumen 105 to the desired location and strongly bonded in the lumen 105 with a bonding agent 142 so that it is held against rotation in the lumen. The bonding agent 142, which may be, for example, vinyl or urethane, can be injected through apertures 143 (Fig. 6) into the lumen 105, and the bonding agent 142 preferably fills the remaining space in the lumen for the full length of the stiffening element 64. The bonding agent 142 also closes the apertures 143.

As shown in Fig. 6, the stiffening element 64 extends farther proximally of the port 72 than distally. By way of example, the stiffening element may extend about 2.5 inches distally from the center of the port 72 and about 1.5 inches proximally from the center of the port 72. The stiffening element 64 extends slightly beyond both of the apertures 143, and the catheter body 101 straightens the stiffening element 64 somewhat into the gentle curve 68 as shown by way of example in Fig. 6. As shown in Fig. 2, the stiffening element

64 lies proximally of the balloon 65, and the thermistor 125 is between the stiffening element and the balloon.

The stiffener lumen 105 need not be diametrically opposite the guiding lumen 109. For example, the stiffener lumen 105 may occupy the position of any of the lumens 103, 105 or 107.

The curved stiffening element 64 generally forms the catheter body 101 into the curve 68 (Figs. 1 and 6). The curve 68 has an inside 68a and an outside 68b, and the port 72 is on the outside 68b of the curve 68 so that the inner catheter 11 will be properly located in the heart. In this embodiment, a radial line 144 through the center 146 (Fig. 8) of the port 72 forms a small angle of about 10 degrees with a radial preference line 148 which bisects the portion of the curve 68 which faces the outside 68b. Preferably, this angle is no greater than about 30 degrees. With this arrangement, the inner catheter 11 exits generally tangent to the curve 68.

The connector tube 119 has a transparent section 145 (Figs. 2 and 3), and the distance between the center of the port 72 and a proximal edge 47 of the transparent section is accurately controlled. In use of the guiding catheter 63, the inner catheter 11 is advanced through the connector tube 119 and the guiding lumen 109 to the port 72 as described in connection with Fig. 1. The inner catheter 11 has a suitable marker which appears at the proximal edge 147 when the distal end 48 is at the port 72. In this manner, the physician knows when the inner catheter 11 is about to exit from the lumen 109 through the port 72.

The connector tube 113 and the through lumen 103 can be used in a conventional manner for various purposes, such as blood pressure monitoring and blood sampling, and the connector tube 115 and the stiffener lumen 105 may be used, for example, to inject an injectate through the injectate port 131 into the superior vena cava 66 or the right atrium 69 for purposes, such as cardiac output measurements by means of thermodilution. The connector tube 117 is coupled to branch tubes 149 and 151 by a conventional connector 153, and the branch tubes 149 and 151 may be used to carry the thermistor wires 129 and for carrying a fluid for inflation and deflation of the balloon 65, respectively.

#### Claims

1. A guiding catheter capable of being passed through the right side of the heart into the pulmonary artery, said guiding catheter comprising :

proximal and distal ends (111, 121), at least one lumen (109) extending longitudinally in the body (101) and a port (72) extending from the lumen (109) to the exterior of the catheter body (101), said port (72) being positioned in relation to the distal end (121) of the catheter such that said port lies in the right ventricle when the catheter extends through the right ventricle into the pulmonary artery;

an elongated stiffening element (64) permanently fixed within the catheter body (101), said stiffening element (64) extending from a location on the proximal side of said port (72) to a location on the distal side of said port, said stiffening element (64) being flexible and sufficiently stiff to cause the catheter to form a gentle curve without forming a kink when the catheter extends through the right ventricle to the pulmonary artery; and

said lumen (109) being such that an inner catheter can be passed through the lumen (109) and the port (72) into the right ventricle,

characterised in that said stiffener element (64) is curved in its unstressed condition so that said catheter body (101) in the region of said port (72) is curved, said stiffener element (64) is held against rotation in the catheter body (101) and said stiffener element (64) resists torsional displacement of the port (72).

2. A guiding catheter according to claim 1 including a balloon (65) on said catheter body (101) distally of the port (72), said catheter body (101) having a balloon inflation lumen means (107) communicating with the balloon (65) for use in inflating the balloon (65) and a thermistor (125) carried by the catheter body (101) intermediate said second location and said balloon (65).
3. A guiding catheter according to claim 1 or claim 2 wherein said catheter body (101) has a stiffener lumen (105) and said stiffener element (64) is in said stiffener lumen (105) and said catheter body (101) has an injectate port (131) which leads from the stiffener lumen (105).
4. A guiding catheter according to any preceding claim wherein a radial line (144) through the center of the port (72) as viewed in a radial plane forms an angle of no more than about 30 degrees with a radial reference line which bisects the portion of the curve which faces outside.

5. A guiding catheter according to any preceding claim wherein said stiffening element (64) in an unstressed condition forms a generally circular arc which extends for over 180 degrees.

6. A guiding catheter according to any preceding claim wherein said stiffening element (64) has a central section of substantially constant stiffness and end portions of lesser stiffness than said central section.

7. A guiding catheter according to any preceding claim including means for at least partially closing said one lumen (109) adjacent said port (72) without closing said port (72) to facilitate the passage of the inner catheter through the port (72) into the right heart.

8. A guiding catheter according to claim 7 wherein said closing means (133) includes a radio-opaque plug.

9. A guiding catheter according to claim 7 or claim 8 wherein said closing means (133) includes a sloping surface (135) facing proximally in said one lumen (109) to facilitate the passage of the inner catheter through the port (72) into the right heart.

#### Revendications

1. Cathéter de guidage pouvant être passé au travers de la partie droite du cœur à l'intérieur de l'artère pulmonaire, ledit cathéter de guidage comprenant :

un corps de cathéter allongé (101) ayant des extrémités proximale et distale (111, 121), au moins une lumière (109) s'étendant longitudinalement dans le corps (101) et un orifice (72) s'étendant depuis la lumière (109) jusqu'à l'extérieur du corps de cathéter (101), ledit orifice (72) étant positionné en relation avec l'extrémité distale (121) du cathéter de telle sorte que ledit orifice soit situé dans le ventricule droit lorsque le cathéter s'étend au travers du ventricule droit à l'intérieur de l'artère pulmonaire ;

un élément de raidissement allongé (64) qui est fixé de manière permanente à l'intérieur du corps de cathéter (101), ledit élément de raidissement (64) s'étendant depuis un emplacement situé sur le côté proximal dudit orifice (72) jusqu'à un emplacement situé sur le côté distal dudit orifice, ledit élément de raidissement (64) étant flexible et suffisamment rigide pour forcer le cathéter à former une incurvation douce sans former une coque lors-

droit jusqu'à l'artère pulmonaire ; et ladite lumière (109) étant telle qu'un cathéter interne puisse être passé au travers de la lumière (109) et de l'orifice (72) à l'intérieur du ventricule droit,

caractérisé en ce que :

ledit élément de raidissement (64) est incurvé dans sa condition sans contrainte de telle sorte que ledit corps de cathéter (101) soit incurvé dans la région dudit orifice (72), ledit élément de raidissement (64) étant maintenu contre toute rotation dans le corps de cathéter (101) et ledit élément de raidissement (64) résistant à tout déplacement par torsion de l'orifice (72).

2. Cathéter de guidage selon la revendication 1, comprenant un ballon (65) situé sur ledit corps de cathéter (101) de manière distale par rapport à l'orifice (72), ledit corps de cathéter (101) comportant un moyen de lumière d'inflation de ballon (107) qui communique avec le ballon (65) pour une utilisation lors de l'inflation du ballon (65) et une thermistance (125) supportée par le corps de cathéter (101) en une position intermédiaire par rapport audit second emplacement et audit ballon (65).
3. Cathéter de guidage selon la revendication 1 ou 2, dans lequel ledit corps de cathéter (101) comporte une lumière d'élément de raidissement (105), dans lequel ledit élément de raidissement (64) est placé dans ladite lumière d'élément de raidissement (105) et dans lequel ledit corps de cathéter (101) comporte un orifice de perfusion (131) qui part de la lumière d'élément de raidissement (105).
4. Cathéter de guidage selon l'une quelconque des revendications précédentes, dans lequel une ligne radiale (144) qui traverse le centre de l'orifice (72) vu selon un plan radial forme un angle de pas plus d'environ 30 degrés avec une ligne de référence radiale qui bissecte la partie de l'incurvation qui fait face à la partie extérieure.
5. Cathéter de guidage selon l'une quelconque des revendications précédentes, dans lequel ledit élément de raidissement (64), lorsqu'il est dans une condition sans contrainte, forme de façon générale un arc circulaire qui s'étend sur 180 degrés.
6. Cathéter de guidage selon l'une quelconque des revendications précédentes, dans lequel ledit élément de raidissement (64) comporte une partie centrale qui présente une rigidité

sensiblement constante et des parties d'extrémité qui présentent une rigidité moindre que la rigidité de ladite partie centrale.

7. Cathéter de guidage selon l'une quelconque des revendications précédentes, comportant un moyen pour au moins partiellement fermer ladite une lumière (109) qui est adjacente audit orifice (72) sans fermer ledit orifice (72) afin de faciliter le passage du cathéter interne au travers de l'orifice (72) à l'intérieur de la partie droite du coeur.
8. Cathéter de guidage selon la revendication 7, dans lequel ledit moyen de fermeture (133) comprend une fiche radiopaque.
9. Cathéter de guidage selon la revendication 7 ou 8, dans lequel ledit moyen de fermeture (133) comporte une surface inclinée (135) qui fait face de manière proximale dans ladite une lumière (109) afin de faciliter le passage du cathéter interne au travers de l'orifice (72) à l'intérieur de la partie droite du coeur.

#### Patentansprüche

1. Führungskatheter, das durch die rechte Seite des Herzens in die Lungenarterie einführbar ist, mit:

einem ein hinteres und ein vorderes Ende (111, 121) aufweisenden langgestreckten Katheterkörper (101), durch den wenigstens ein Kanal (109) in Längsrichtung verläuft und zu dessen Äußerem eine vom Kanal (109) ausgehende Öffnung (72) führt, die relativ zum vorderen Ende (121) des Katheters so angeordnet ist, daß die Öffnung in der rechten Herzkammer liegt, wenn das Katheter durch diese in die Lungenarterie eingeführt ist, mit einem permanent im Katheterkörper (101) befestigten langgestreckten Versteifungselement (64), das von einer Stelle am hinteren Ende der Öffnung (72) zu einer Stelle am vorderen Ende der Öffnung verläuft und flexibel und ausreichend steif ist, um dem Katheter eine sanfte Kurve ohne Knick zu geben, wenn es durch die rechte Herzkammer in die Lungenarterie verläuft,

und mit einer derartigen Ausbildung des Kanals (109), daß ein Innenkatheter durch ihn und die Öffnung (72) in die rechte Herzkammer einführbar ist,

dadurch gekennzeichnet, daß das Versteifungselement (64) in spannungslosem Zustand so gebildet ist, daß der Katheterkörper (101)

im Bereich der Öffnung (72) gekrümmt ist, und das Versteifungselement (64) gegen Drehung im Katheterkörper (101) gehalten ist und eine Torsionsverschiebung der Öffnung (72) verhindert.

2. Führungskatheter nach Anspruch 1 mit einem gegen die Öffnung (72) versetzt angeordneten Ballon (65) auf dem Katheterkörper (101), einem Ballonaufblaskanal (107) im Katheterkörper (101), der zum Aufblasen des Ballons (65) mit diesem in Verbindung steht, und mit einem vom Katheterkörper (101) zwischen der zweiten Stelle und dem Ballon (65) getragenen Thermistor (125). 10 15
3. Führungskatheter nach Anspruch 1 oder 2, bei dem der Katheterkörper (101) einen Versteifungskanal (105) aufweist, das Versteifungselement (64) sich im Versteifungskanal (105) befindet und der Katheterkörper (101) eine vom Versteifungskanal (105) wegführende Injektionsöffnung (131) aufweist. 20
4. Führungskatheter nach den vorhergehenden Ansprüchen, bei dem in einer Radialebene gesehen, eine durch die Mitte der Öffnung (72) verlaufende Radiallinie (141) einen Winkel von nicht mehr als etwa 30° mit einer radialen Bezugslinie bildet, die den nach außen weisenden Teil der Kurve in zwei Teile teilt. 25 30
5. Führungskatheter nach den vorhergehenden Ansprüchen, bei dem das Versteifungselement (64) im spannungslosen Zustand einen generell kreisförmigen sich über 180° erstreckenden Bogen bildet. 35
6. Führungskatheter nach den vorhergehenden Ansprüchen, bei dem das Versteifungselement (74) einen mittleren Abschnitt mit im wesentlichen konstanter Steifigkeit sowie Endteile mit gegenüber dem mittleren Teil kleinerer Steifigkeit besitzt. 40 45
7. Führungskatheter nach den vorhergehenden Ansprüchen mit einer Einrichtung zum wenigstens teilweise Verschließen des der Öffnung (72) benachbarten einen Kanals (109) ohne Verschließen der Öffnung (72), um den Durchtritt des inneren Katheters durch die Öffnung (72) in das rechte Herz zu erleichtern. 50
8. Führungskatheter nach Anspruch 7, bei dem die Verschließeinrichtung (133) ein strahlungs- undurchlässiger Stöpsel ist. 55

9. Führungskatheter nach Anspruch 7 oder 8, bei dem die Verschließeinrichtung (133) eine dem einen Kanal (109) zugekehrte geneigte Fläche (135) besitzt, um den Durchtritt des inneren Katheters durch die Öffnung (72) in das rechte Herz zu erleichtern.







